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<u>L5</u>	L4 with l3	19	<u>L5</u>
<u>L4</u>	drug or negatively charged or dna or nucleic or gene or polynucleotide	512632	<u>L4</u>
<u>L3</u>	L2 with l1	620	<u>L3</u>
<u>L2</u>	inner layers or alterna\$ layer	83303	<u>L2</u>
<u>L1</u>	catheter or stent or medical device	103221	<u>L1</u>

END OF SEARCH HISTORY

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L5: Entry 5 of 19

File: PGPB

May 23, 2002

DOCUMENT-IDENTIFIER: US 20020061326 A1

TITLE: Controlled delivery of therapeutic agents by insertable medical devices

Abstract Paragraph (1):

A medical device and method for transportation and release of a therapeutic agent into a mammalian body are disclosed. The medical device is coated with alternating layers of a negatively charged therapeutic agent and a cationic polyelectrolyte, following a controlled adsorption technique. The method is simple, with minimal perturbation to the therapeutic agent and uses clinically acceptable biopolymers such as human serum albumin. The amount of the therapeutic agent that can be delivered by this technique is optimized by the number of the layers of the therapeutic agent adsorbed on the surface of medical device. There is a washing step between alternate layers of the therapeutic agent and cationic polyelectrolyte carrier, so that the amount of the therapeutic agent on the insertable medical device represents the portion that is stably entrapped and adsorbed on to the medical device. The insertable medical device and method according to this invention are capable of reproducibly delivering therapeutic agent to a site in a mammalian body, and allow for a highly reproducible and controllable release kinetics of the therapeutic agent.

Summary of Invention Paragraph (10):

[0006] In one aspect, the present invention provides a method of delivering a negatively charged therapeutic agent to a target location within a mammalian body. The method comprises the steps of applying a multiplicity of alternating layers of at least one cationic polyelectrolyte carrier and a multiplicity of layers of a negatively charged therapeutic agent to at least one surface of an insertable medical device. A washing step is employed between application of the cationic polyelectrolyte and the negatively charged therapeutic agent. The medical device is delivered to a target site within the body, and upon reaching the target site the negatively charged therapeutic agent is released into the target site. The negatively charged therapeutic agent remains qualitatively and quantitatively intact during the stages of coating, washing, delivery and release.

Summary of Invention Paragraph (15):

[0011] Another preferred embodiment of this invention provides an insertable medical device for insertion into a mammalian body, wherein the insertable medical device has a multiplicity of alternating layers of at least one cationic polyelectrolyte and a biologically effective amount of a negatively charged therapeutic agent, which are adsorbed on to a surface of the insertable medical device. The amount of adsorbed negatively charged therapeutic agent increases linearly with the number of the layers of same applied and entrapped onto the surface of the medical device.

## CLAIMS:

10. A method of adsorbing a negatively charged therapeutic agent onto the surface of a medical device comprising: (a) coating at least one portion of at least one surface of a medical device with a cationic polyelectrolyte carrier to form an inner layer of cationic polyelectrolyte carrier; (b) washing the layer of cationic polyelectrolyte carrier with a washing solution; (c) adsorbing one or more negatively charged therapeutic agent onto the layer of cationic polyelectrolyte carrier to form a layer of therapeutic agent; and optionally (d) washing the layer of therapeutic agent with a washing solution and repeating steps (a) through (c) one or more times to form multiple layers of cationic polyelectrolyte carrier and therapeutic agent.

desired amount of therapeutic agent has been adsorbed onto the medical device.

19. A medical device comprising a negatively charged therapeutic agent adsorbed on the surface thereof and produced by a process comprising: (a) coating at least one portion of at least one surface a medical device with a cationic polyelectrolyte carrier to form an inner layer of cationic polyelectrolyte carrier; (b) washing the layer of cationic polyelectrolyte carrier with a washing solution; (c) adsorbing one or more negatively charged therapeutic agent onto the layer of cationic polyelectrolyte carrier to form a layer of therapeutic agent; and optionally (d) washing the layer of therapeutic agent with a washing solution and repeating steps (a) through (c) one or more times to form multiple layers of cationic polyelectrolyte carrier and therapeutic agent until a desired amount of therapeutic agent has been adsorbed onto the medical device.

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L5: Entry 18 of 19

File: DWPI

Jul 12, 2001

DERWENT-ACC-NO: 2001-475951

DERWENT-WEEK: 200239

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TITLE: New implantable medical device coated with layers of a cationic polyelectrolyte carrier and at least one negatively charged therapeutic agent, useful as a stent, catheter, balloon catheter or combination of these.

Basic Abstract Text (1):

NOVELTY - A new implantable medical device coated with alternating layers of a negatively charged therapeutic agent and a cationic polyelectrolyte.

Equivalent Abstract Text (1):

NOVELTY - A new implantable medical device coated with alternating layers of a negatively charged therapeutic agent and a cationic polyelectrolyte.